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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/657,759 | 09/08/2003 | David Lewis | 48924-01030 | 1172 |

7590 09/22/2004

HOLME ROBERTS & OWEN, LLP
Suite 1800
299 South Main Street
Salt Lake City, UT 84111

EXAMINER

HAGHIGHATIAN, MINA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,759

Applicant(s)

LEWIS ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/03, 12/03</u> | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 11-14, 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager et al (5,955,058) in view of Lasserre et al (6,296,156).

Jager discloses a stabilized medicinal aerosol solution formulations comprising medicaments that degrade or decompose by interacting with solvents or water, an HFA propellant, a cosolvent and an acid. The active agent suitable for such a formulation is ipratropium bromide, however other active agents such as steroids may be added (see col. 2, lines 43-54 and col. 4, lines 1-58). The solvents include ethanol, propylene glycol, glycerol, etc (col. 4, line 62 to col. 5, line 14). Jager discloses that a suitable aerosol container is needed, however is silent with regards to the specific container.

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Lasserre et al teaches a mounting device for mounting a valve on a container and a dispenser containing a product under pressure fitted with such a mounting device. The inner surface of the cup which comes in contact with the product is coated with a lacquer or some other inert thermoplastic layer (col. 1, lines 63-65). The container containing a product, particularly a liquid, placed under pressure by a conventional propellant, to be dispensed by actuation of the dispensing valve. The open end of the container is formed by a neck, the said neck having a profile capable of engaging with a portion formed on the said external first mounting means. The neck of the container may be rolled outwards with respect to the central axis of the container or alternatively may be rolled inwards with respect to the axis of the container. The neck of the container has an edge bent towards the central axis of the container (col. 4, lines 1-34). The container may be a one-piece aluminum can. The cup is made of plastic, such as polyacetal (col. 4, lines 63-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of Jager's aerosol solution formulations with a suitable aerosol container, to have looked in the art for a more specific container, with the reasonable expectations of successfully preparing a product that is stable and has a long shelf life.

Claims 8-10 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager et al (5,955,058) in view of Lasserre et al (6,296,156) as applied to claims 1-7, 11-14, 17-23 above, and further in view of Britto (6,149,892).

The combined references discussed above, lack specific disclosure on the use of 20-ketosteroid corticosteroid and the polymers used for inner coating.

Britto teaches a metered dose inhaler having part or all of its internal surfaces coated with one or more fluorocarbon polymers, optionally in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation comprising beclomethasone dipropionate (col. 1, lines 59-67). The formulations may contain other medicaments such as fluticasone, triamcinolone acetonide, etc (col. 3, lines 6-10). The aerosol can and cap are made of aluminum or an alloy of aluminum (col. 3, lines 61-67). The fluorinated polymers for use as coating agents include polytetrafluoroethylene (PTFE), fluorinated ethylenepropylene, etc (col. 4, lines 22-38).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the solution formulations of Jager with the aluminum canister of Lasserre, to have looked in the art for specific polymers for inner surface coating of the containers and other suitable active agents such as triamcinolone acetonide, as taught by Britto, with the reasonable expectations of preparing effective formulations for storing and delivering in a suitable and degradation resistant container.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/290,225 in view of Lasserre et al (6,296,156). The examined claims are drawn to a solution formulation comprising an active agent, a cosolvent, optionally a low volatility agent in an aerosol canister having a rim with rounded edges. The claims of copending Application No. 10/290,225 are drawn to the same formulation without reference to the rim or neck of the canister. Lasserre discloses an aluminum canister for aerosol devices with a rolled neck. Therefore it would have been obvious to implement the canister of Lasserre for the formulations of the instant claims such that a stable formulation with long shelf life is provided.

This is a provisional obviousness-type double patenting rejection.

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Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/244,519 in view of Lasserre et al (6,296,156). The examined claims are drawn to a solution formulation comprising an active agent, a cosolvent, optionally a low volatility agent in an aerosol canister having a rim with rounded edges. The claims of copending Application No. 10/244,519 are drawn to the same formulation without reference to the rim or neck of the canister. Lasserre discloses an aluminum canister for aerosol devices with a rolled neck. Therefore it would have been obvious to implement the canister of Lasserre for the formulations of the instant claims such that a stable formulation with long shelf life is provided.


This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

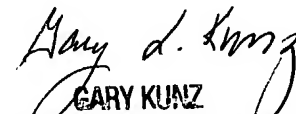
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
September 20, 2004



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600